NOXtec by ND

NOXtec 1000

Automatic or Manual dosing Nitric Oxide Monitor

Electromedicine

Dose System						Monitor system	
Real time Mode	Automatic Mode	Semi-automatic Mode	Manual Mode	Cylinder Exchange	Automatic Venting	Automatic Calibration	Room measurement
✓	✓	✓	✓	✓	✓	✓	✓

NOXtec 1000 is a medical device which both **dosifies and monitors the supply of nitric oxide (NO)**.

NO is a gaseous vasodilator used to treat pulmonary arterial hypertension. It is supplied to the patients mixed with medical oxygen. NOXtec 1000 supplies a **stable dosis** throughout the therapy, even triggering an **automatic exchange of the cylinders** (it can harbour two cylinders) if needed.

NOXtec **calculates automatically the necessary dosing flow**, thanks to a **disposable breathing flow sensor** applied to the patient's circuit. Alternatively, the dosing flow can be set manually.

Thanks to the **continuous sampling of the NO-O_2 mixture flow** supplied, NOXtec is able to monitorize the NO concentration that the patient is receiving, and to check if this value is placed within predetermined thresholds.

NOXtec 1000 also **monitors trace quantities of nitrous oxide (NO_2)** in the mixture, a highly toxic gas which can compromise the patient's safety during the treatment. NOXtec 1000 triggers and alarm when this trace surpasses a threshold value.

MAIN FEATURES

- **Dosing and monitoring modules and user interface independent from each other to guarantee the patient's safety.**
- **Automatic cylinder exchange** to increase the treatment autonomy and optimize the gas consumption.
- **Automatic venting procedure** to minimize the NO_2 supplied to the patient at the beginning of the treatment and during the cylinder exchange, and also to depressurize the system when the device is not in use.
- **Automatic calibration of the NO, NO_2 and O_2 sensors**, available even when the device is dosing.
- Dosing mode options: Real time, Automatic, Semi-automatic or Manual.
- **NOXtec includes an emergency manual dosing mode**, which can be used even when the device is off.
- **Negligible liberation of NO to the environment.** The device includes a purge outlet to gather and canalize the residual gas.
- **Measurement of the concentration of NO, NO_2 and O_2 in the room.**
- **Hot wire and differential pressure technologies for the external breathing flow sensors.**
- Ethernet port for **remote technical assistance**.
- USB port to retrieve **therapy data files.**

NOXtec 1000: Basic Set

Reference	Description	Qty
01NXTC1000	NOXtec 1000: Nitric Oxyde Monitor with Automatic Deliver System. *Main Box with pneumatic, electronic and user interface.*	1
01NTMNPG0A	Manifold with calibration gas sensors: NO, NO_2 y O_2, including PCB battery power.	1
01NTDSEG1D	Flow sensor cable.	1
01NTDSEGxx	Power cable "xx".	1
10BiT3xxxx0X	Stainless steel gas regulator for NO supply, with high pressure sensor incorporated.	2

NOXtec 1000: Calibration Set

Reference	Description	Qty
10Bi02****0X	Stailess steel gas regulator for gas de calibration.	1
01NTMNPG19	Gas calibration 5 L cylinder, 70 ppm of NO and 10 ppm of NO_2 in N_2.	1

NOXtec 1000: Optional Set

Reference	Description	Qty
01NTCG0000	Trolley for holding the device, space for 2 x 20 L cylinders, 1 x 5L calibration cylinder and 1x 5 L backup oxygen cylinder *(cylinders not included)*.	1

TECHNICAL SPECIFICATIONS

PHYSICAL SPECIFICATIONS

Dimensions and weight:

- **Main unit:** 205 x 300 x 345 mm; 9,2 kg.
- **Cart:** 1250 x 570 x 630 mm; 47,5 kg

Cart's capacity for cylinders: 2 cylinders of 20 L

Materials: AISI 304 and AISI 316L stainless steel, PTFE and ABS.

Screen: Touch colour 10,1" screen

DOSING MODULE

Dosing options:

- Real Time
- Automatic
- Semiautomatic
- Manual

Measuring range:

- Automatic: 0 - 4 L/min
- Manual: 0 - 0,02 - 0,03 - 0,05 - 0,07 - 0,1 - 0,15 - 0,2 - 0,25 - 0,3 - 0,45 - 0,6 L/min

NO dosing interval: 0-100 ppm (upgradeable upon request)

Dosing accuracy: ±5%

Dosing resoluion: 0,1 ppm

Ventilation flow rates:

	Adult	Paediatrical and neonatal
Differential pressure	2,0-120 l/min	0,5-60 L/min
Hot wire	0,5-100 l/min	0,2-60 L/min *(not available yet)*

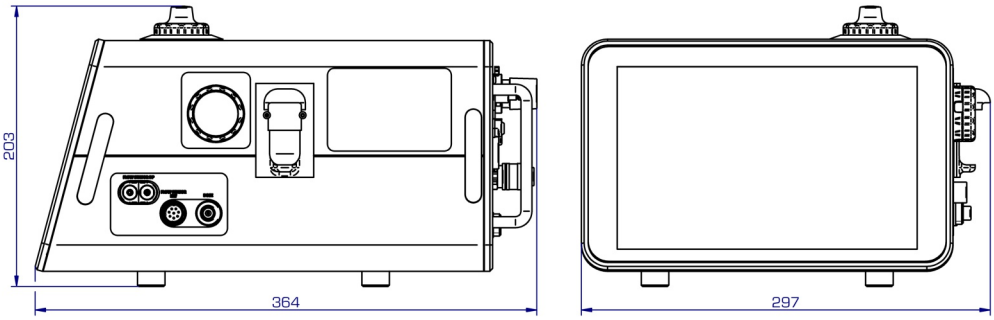
Set up time: < 2 min fs

MONITORIZATION MODULE

	Gas sensor type	Measuring range	Measuring accuracy	Resolution	Response time
NO	Electrochemical cell	0-160 ppm	±10% + 0,5 ppm	0,1 ppm	<10s
NO_2	Electrochemical cell	0-20 ppm	±10% ó ±0,2 ppm (whichever is higher)	0,1 ppm	<40s
O_2	Electrochemical cell	0-100%	±3,5%	1%	<20s

Sampling flow: 90 - 250 mL/min (configurable, 150 mL/min by default)

Operational life of the sensors: 12 months



Operating and storage conditions

Operating conditions: 10 - 40ºC; 15 - 90% de humidity

Storage conditions: -10 - 60ºC; 15 - 90% humidity

Electrical specifications

Power: 100-240 VAC, 50-60 Hz

Battery:

- Duration: 4h
- Charging time: 2,5 h approx.

Classification: Clase I, type B

Electromagnetic and RF specifications

Guidance and manufacturer's declaration - electromagnetic emissions

NOXtec is intended to be used in the electromagnetic environment specified below. The client or the user of NOXtec should ensure that it is utilized in such environment.

Emission Test	Accordance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	NOXtec uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR	Class B	NOXtec is suitable for use in all establishments, including domestic establishments and those directly connected to the low-voltage public network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emission IEC 61000-3-3	Meets	

In compliance

CEN/TS 14507-1:2003
CEN/TS 14507-2:2003
UNE-EN 60601-1:2008/A12:2015
IEC 60601-1-8:2006+A1:2012
IEC 60601-1-6:2010/A1:2013
IEC 62366-1:2015
IEC 62304:2006/A1:2015
UNE-EN 55011:2016/A1:2017
UNE-EN 61000-3-3:2013
UNE-EN 61000-4-2:2010
UNE-EN 61000-4-3:2007/A1:2008/A2:2011
UNE-EN 61000-4-4:2013
UNE-EN 61000-4-5:2015
UNE-EN 61000-4-6:2014
UNE-EN 61000-4-8:2011
UNE-EN 61000-4-11:2005
UL requirements
RoHS Directive

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